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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/025,947

12/26/2001

Hsuan-Yin Lan-Hargest

12938-003002

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10/19/2009

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WASHINGTON, DC 20036

EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

10/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/025,947	<b>Applicant(s)</b> LAN-HARGEST ET AL.	
	<b>Examiner</b> Paul A. Zucker	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/17/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 August 2009 has been entered.

***Current Status***

2. This action is responsive to Applicants' amendment of 17 August 2009.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending.
5. The rejection under 35 USC § 112, second paragraph, set forth in paragraph 6 of the previous Office Action mailed 18 June 2009 is withdrawn in response to Applicant's amendment.
6. The rejection under 35 USC § 112, first paragraph, set forth in paragraph 7 of the previous Office Action mailed 18 June 2009 is withdrawn in response to Applicant's amendment.
7. The rejections under 35 USC § 102, set forth in paragraphs 8-10 of the previous Office Action mailed 18 June 2009 are withdrawn in response to Applicant's amendment.

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***New Rejections***

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the limitation excluding the subgenii defined in lines 23 -32 and 22-30, respectively :

“that when L contains three double bonds, said hydrocarbon chain is further substituted with C<sub>2-4</sub> alkenyl, C<sub>2-4</sub> alkynyl, C<sub>1-4</sub> alkoxy, hydroxyl, halo, amino, nitro, C<sub>3-5</sub> cycloalkyl, 3-5 membered heterocycloalkyl, monocyclic aryl, 5-6 membered heteroaryl, C<sub>1-4</sub> alkylcarbonyloxy, C<sub>1-4</sub> alkylcarbonyl, or formyl; and further provided that when L is C<sub>4</sub> or C<sub>5</sub> ~~C<sub>3-7</sub>~~ and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl, Y<sup>1</sup> is not a bond or -CH<sub>2</sub>- and Y<sup>2</sup> is -CH<sub>2</sub>-; provided that when L is C<sub>4</sub>, A is C<sub>3-14</sub> cycloalkyl then Y<sub>1</sub> is not CH<sub>2</sub>; and further provided that when L is C<sub>4</sub> containing two double bonds, and is ω-substituted with phenyl or substituted phenyl, A is not phenyl or substituted phenyl;”.

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The claim language constitutes new matter because the written description of the instant specification does not “reasonably lead” those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

9. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the limitation excluding the subgenii defined in lines 16 -19 :

“that when L contains three double bonds, said hydrocarbon chain is further substituted with  $C_{2-4}$  alkenyl,  $C_{2-4}$  alkynyl,  $C_{1-4}$  alkoxy, or amino; and further provided that when L is  $C_4$  or  $C_5$   ~~$C_{3-7}$~~  and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl,  $Y^1$  is not a bond or  $-CH_2-$ , and  $Y^2$  is  $-CH_2-$ .”

The claim language constitutes new matter because the written description of the instant specification does not “reasonably lead” those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

10. Claims 80, 91 and 103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support

for the limitation excluding the subgenii defined in lines 23 -27, 21-25 and 18-22, respectively :

provided that when L is C<sub>4</sub>, A is C<sub>3-14</sub> cycloalkyl then Y<sub>1</sub> is not CH<sub>2</sub>; and further provided that when L is C<sub>4</sub> containing two double bonds, and is ω-substituted with phenyl or substituted phenyl, A is not phenyl or substituted phenyl; further provided that when L is C<sub>4</sub> or C<sub>5</sub> C<sub>3-7</sub> and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl, Y<sup>1</sup> is not a bond or -CH<sub>2</sub>- and Y<sup>2</sup> is -CH<sub>2</sub>-,"

The claim language constitutes new matter because the written description of the instant specification does not "reasonably lead" those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

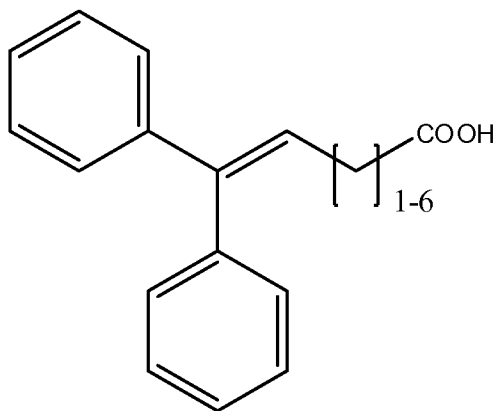
11. Claims 1-5, 12, 13, 16, 17, 22, 25, 26, 80-84, 88-94, 99, 102 and 103 and are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al (US 4,931,469 06-1990). Black discloses (Column 10, lines 49-59), the compound 7-phenylhept-2E-en-6-ynoic acid and its potassium salt in aqueous solution corresponding to a pharmaceutical composition. 7-Phenylhept-2E-en-6-ynoic acid corresponds to instantly claimed compounds in which A is phenyl (unsubstituted), L is a C<sub>6</sub> trans olefin containing a triple bond, Y<sup>1</sup>, Y<sup>2</sup>=a bond (or L is a C<sub>5</sub> trans olefin, Y<sup>1</sup>=a bond,

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$Y^2=CH_2$ ),  $X_1, X_2 = O$ . Black therefore anticipates claims 1-5, 12, 13, 16, 17, 22, 25, 26, 80-84, 88-94, 99, 102 and 103.

12. Claims 1-5, 7-8, 12, 13, 16, 17, 22, 25, 26, 80-84, 85-86, 88-94, 99, 102 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitigawa et al (JP 11-049719-A 02-1999, Machine translation). Kitigawa discloses (Paragraph [0012]) the compounds 7-phenyl-4,6- heptadienoic acid, 8-phenyl-5,7- octadienoic acid, 9-phenyl-6,8- nonadienoic acid and 10-phenyl-7,9- decadienoic acid corresponding to instantly claimed compounds in which A is phenyl (unsubstituted), L is a  $C_{6-10}$  all trans diene containing a triple bond,  $Y^1, Y^2=a$  bond (or L is a  $C_{5-9}$  all trans olefin,  $Y^1=a$  bond,  $Y^2=CH_2$ ),  $X_1, X_2 = O$ . Kitigawa discloses (Paragraph [0011]) their solutions as salts in water corresponding to pharmaceutical compositions. Kitigawa therefore anticipates claims 1-5, 7-8, 12, 13, 16, 17, 22, 25, 26, 80-84, 85-86, 88-94, 99, 102 and 103

13. Claims 1-5, 12, 13, 22, 80-84, 88, 91-94, 96, 97, and 99-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Guthrie et al (US 4,927,838 05-1990). Guthrie discloses (Column 59, lines 1-15, column 60, lines 5-57) the compounds:



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corresponding to instantly claimed compounds in which A is phenyl (unsubstituted), L is a monocyclic aryl substituted C<sub>3-7</sub> all trans diene containing a Y<sup>1</sup>, Y<sup>2</sup>=a bond (or L is a C<sub>2-6</sub> all trans olefin, Y<sup>1</sup>=a bond, Y<sup>2</sup>=CH<sub>2</sub>), X<sub>1</sub>, X<sub>2</sub> = O. Guthrie discloses recrystallization solutions of the compounds which the Examiner considers to correspond to pharmaceutical compositions. Guthrie therefore anticipates claims 1-5, 12, 13, 22, 80-84, 88, 91-94, 96, 97, and 99-103.

### ***Claim Objections***

14. Claims 1, 22, 80, 91, 102 and 103 are objected to because of the following informalities: Each of the enumerated claims recites the limitation "Y<sub>1</sub>" in its proviso section. This should be amended to "Y<sup>1</sup>" in each case in order to correspond to structure of formula (I). Appropriate correction is required.

### ***Conclusion***

15. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-84, 87-94, 96, 97 and 99-103 are finally rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/  
Primary Examiner, Art Unit 1621